UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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FERRING B.V., FERRING INTERNATIONAL CENTER S.A., and FERRING PHARMACEUTICALS INC.,

Plaintiffs and Counter-Defendants,

-against-

SERENITY PHARMACEUTICALS, LLC, REPRISE BIOPHARMACEUTICS, LLC, AVADEL SPECIALTY PHARMACEUTICALS, LLC

Defendants and Counterclaimants.

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17 Civ. 9922

OPINION and ORDER

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Plaintiffs Ferring B.V., Ferring International Center S.A., and Ferring Pharmaceuticals Inc. ("Ferring," or the "Plaintiffs") and Defendants Serenity Pharmaceuticals, LLC ("Serenity"), Reprise Biopharmaceutics LLC ("Reprise"), Avadel Specialty Pharmaceuticals LLC ("Avadel") (together, "Defendants," or "Counterclaim Plaintiffs") move for claim construction with respect to two of Defendants' patents, U.S. Patent Nos. 7,405,203 (the "203 Patent") and 7,579,321 (the "321 Patent"). In dispute are certain terms from claims 1, 2, 6, 9, 10, 12, 13, and 15 of the 203 Patent and claims 1, 2, 6-8, 12, and 15-19 of the 321 Patent (the "Asserted Claims").

Pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996), the parties submitted briefing in support of their proposed construction of the disputed claim terms. A Markman hearing was held on November 13, 2018, at which point the motion was marked fully submitted.

What follows is the Court's construction of the disputed preamble and claim terms.

I. The Patents in Suit

On May 7, 2002, Ferring filed a Great Britain Patent Application No. GB0210397.6 (the "GB Application"), for a "pharmaceutical dosage form of desmopressin adapted for sublingual absorption," with no inventor named. 166 F. Supp. 3d at 417. In the following months and years, Dr. Fein and Ferring filed several patents involving this subject matter. See Ferring B.V. v. Allergan, Inc., No. 12 Civ. 2650 (RWS), 2015 WL 5671799, at *2-*3 (S.D.N.Y. Sept. 22, 2015) (detailing the many Dr. Fein and Ferring patents).

On September 20, 2002, Ferring filed PCT Application IB02/04036, claiming the same subject matter as the GB Application and naming Dr. Fein as one of its inventors. Ferring v. Allergan, 253 F. Supp. 3d 708, 711 (S.D.N.Y. 2015).

On May 7, 2003, Ferring filed a modified PCT Application IB03/02368 (the "PCT Application") that claimed priority to the GB Application, but did not include low dose and sublingual claims. Ferring, 166 F. Supp. 3d at 418. Nor did it name Dr. Fein as an inventor. Id.

On November 12, 2003, Dr. Fein, through counsel, filed continuation-in-part U.S. patent application 10/706,100 based off his PCT application US2003/014463. Ferring v. Allergan, 253 F.Supp.3d 708, 713 (S.D.N.Y. 2015). U.S. patent application 10/706,100 issued as U.S. Patent Application 2004/0138098 A1 on July 15, 2004. Id.

On May 4, 2007, Dr. Fein, through counsel, filed U.S. patent application 11/744,615 as a division of his previously filed U.S. patent application 10/706,100. Id.

On July 15, 2008, Dr. Fein, through counsel, filed U.S. patent application 12/173,074 as a continuation of his previously filed U.S. patent application 11/744,615. Id.

On July 29, 2008, Dr. Fein's U.S. patent application 11/744,615 issued as U.S. Patent No. 7,405,203 ("203 patent"). Id.

On June 18, 2009, Ferring filed U.S. patent application 12/487,116 as a continuation of its previously filed U.S. patent application 10/513,437. Id. at 712.

On August 25, 2009, Dr. Fein's patent application 12/173/074 issued as U.S. Patent No. 7,579,321 ("321 patent"). Id.

On October 12, 2010, Adriana Burgy of Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., counsel of record for Ferring, filed a request for reexamination of Dr. Fein's '203 patent before the United States Patent and Trademark Office ("PTO"). Id.

On January 19, 2011, the PTO denied Ferring's request for reexamination of the '203 patent. Id.

On May 24, 2011, Ferring's U.S. patent application 12/487,116 issued as U.S. Patent No. 7,947,654 ("the '654 patent"). Lloyd Decl. Ex. 10 at 2. Id.

II. The Applicable Standard

Claim construction is an issue of law to be determined by the court. Markman, 517 U.S. at 385. In interpreting the meaning of claim terms, "words of a claim 'are generally given their ordinary and customary meaning'" as understood by "a

person of ordinary skill in the art at the time of invention, i.e., as of the effective filing date of the patent application." Phillips v. AWH Corp., 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (citations omitted). The court reads a claim term "not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Id. at 1313.

The Federal Circuit has emphasized the importance of "intrinsic" evidence in claim construction: the words of the claim themselves, the written description in the patent's specification, and, when necessary, the history of the patent application's prosecution before the U.S. Patent and Trademark Office (the "PTO"). Id. at 1314-17.

The process of claim construction begins with the language of the claims themselves, which the patentee selected to "'particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention.'" Id. at 1311-12 (quoting 35 U.S.C. § 112, ¶ 2). Thus, "the claims themselves provide substantial guidance as to the meaning of particular claim terms." Id. at 1314. In addition to the

particular claim being examined, the context provided by other claims may be helpful as well. Id.

Claim language must also be read in the context of the specification. Id. at 1315. The specification "is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term." Id. (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). When the patentee "act[s] as his or her own lexicographer" and includes an explicit definition of a claim term in the specification, that definition is dispositive. Id. at 1319 (citation omitted). The specification also acts as a dictionary "when it defines terms by implication." Vitronics, 90 F.3d at 1582. However, when using the specification to interpret claim terms, a court should not confine its interpretation to embodiments described in the specification. Phillips, 415 F.3d at 1323. In addition, the mistake of "reading a limitation from the written description into the claims" is "one of the cardinal sins of patent law." Id. at 1320 (quoting SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1340 (Fed. Cir. 2001)); see also Thorner v. Sony Comput. Entm't Am. LLC, 669 F.3d 1362, 1366-67 (Fed. Cir. 2012) ("we do not read limitations

from the specification into the claims; we do not redefine words.").

Courts may also utilize the prosecution history, which "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Id. at 1317 (citations omitted). However, the prosecution history "often lacks the clarity of the specification and thus is less useful for claim construction purposes." Id.

Finally, courts may rely on "extrinsic" evidence such as dictionaries, learned treatises, and expert testimony, which may serve as a source of "accepted meaning of terms used in various fields of science and technology" or provide "background on the technology at issue." Id. at 1317-18. However, such extrinsic evidence is "less significant than the intrinsic record in determining the legally operative meaning of the claim language." Id. at 1317 (internal citations and quotation marks omitted). Extrinsic evidence may not be used to contradict the meaning of the claim terms as evidenced by the intrinsic

evidence. Id. at 1317-19; see also Biagro W. Sales, Inc. v. Grow More, Inc., 423 F.3d 1296, 1302 (Fed. Cir. 2005).

III. Disputed Claim Terms

The parties stipulate that the following claim term preambles are "limiting" and are to be given their plain and ordinary meaning by the Court: "a method of treating nocturia, primary nocturnal enuresis, or incontinence, or for inducing voiding postponement, said method comprising," found in claim 1 of the 203 Patent; "a method for inducing an antidiuretic effect in a patient comprising," found in claim 10 of the 203 Patent; "a method for treating a patient suffering from nocturia comprising," found in claim 13 of the 203 Patent; "a method for inducing voiding postponement comprising," from claim 8 of the 321 Patent; and "reducing the risk that the patient develops hyponatremia," from claims 1 and 19 of the 321 Patent.

The parties agree that the following claim term preamble is "limiting," but disagree over whether it should be given its plain and ordinary meaning: "a method for inducing voiding postponement in a patient while reducing the risk that

the patient develops hyponatremia comprising," from claims 1 and 19 of the 321 Patent.

The parties dispute the meaning of the following claim terms: "transmucosal," found in claims 2, 6, 10, and 13 of the 203 Patent and claims 1, 12, and 19 of the '321 Patent; "transmucosal delivery"/ "transmucosal . . . delivery," found in claims 2, 6, 10, and 13 of the 203 Patent; "delivering to the bloodstream . . . by transmucosal . . . administration," found in claims 1 and 19 of the 321 Patent; "transmucosal administration"/ "administering . . . by transmucosal administration," found in claim 12 of the 321 Patent; "a dose of desmopressin sufficient to achieve a maximum desmopressin plasma/ serum concentration no greater than 10 pg/ml," found in claim 1 of the '203 Patent; "desmopressin . . . in an amount . . . sufficient to establish a maximum serum/ plasma desmopressin concentration no greater than 10 pg/ml," found in claim 10 of the 203 Patent; "desmopressin pharmaceutical composition . . . in an amount . . . sufficient to establish a serum/plasma desmopressin concentration no greater than about 5 pg/ml," found in claim 12 of the 203 Patent; "desmopressin . . . in an amount . . . sufficient to establish a maximum serum/ plasma desmopressin concentration greater than 0.1 pg/ml and less than

10 pg/ml," found in claim 13 of the 203 Patent; "delivering to the bloodstream of the patient an amount of desmopressin no more than about 2 ng/kg . . . said amount being therapeutically effective to produce an antidiuretic effect," found in claim 1 of the 321 Patent; "delivering to the bloodstream of the patient an amount of desmopressin no greater than about 1 ng/kg," found in claim 2 of the 321 Patent; "an amount of desmopressin sufficient to produce in the patient a urine osmolality ranging above about 300 mOsm/kg," found in claim 8 of the 321 Patent; "delivering to the bloodstream of the patient . . . no more than about 1 ng/kg desmopressin to produce an antidiuretic effect," found in claim 19 of the 321 Patent; about 2 ng/kg desmopressin," found in claims 1 and 17 of the 321 Patent; and finally, "about 1 ng/kg desmopressin," found in claims 2 and 19 of the 321 Patent.

IV. Claim Construction

a. The Preambles

The only issue to be resolved with respect to the individual claim preambles is the meaning of the shared preamble from claims 1 and 19 of the 321 Patent (the "Shared Preamble"). Tr. 2:16-20 ("[Parties] have agreed that they are limiting, and

they get their plain and ordinary meaning. But there is one preamble in the '321 patent that is a method of inducing voiding postponement while reducing the risk of hyponatremia, and we do have a construction for that based on Dr. Fein's representations to the patent office, etc.").

"a method for inducing voiding postponement in a patient while reducing the risk that the patient develops hyponatremia comprising"

The disagreement turns on whether the Shared Preamble should be given its plain and ordinary meaning, or, as Ferring proposes, a dose limitation should be read into the Shared Preamble. Ferring's Presentation at Oral Argument, Nov. 13, 2018, ECF No. 199-8. (inserting into the preamble the phrase "*by administering a low dose of desmopressin (i.e., less than 20 µg)*").

Ferring's proposed construction of the Shared Preamble was presented for the first time at the Markman hearing in an oral argument supplement.[1]

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[1] The parties' Joint Disputed Claims Chart (ECF No. 158-1), which purported to address the disputed claim terms and proposed constructions, did not include Ferring's proposed construction for the Shared Preamble. Nor did the briefing. ECF No. 198.

Ferring proposes that "a method for inducing voiding postponement in a patient while reducing the risk that the patient develops hyponatremia comprising," be construed to mean "a method for inducing voiding postponement in a patient while reducing the risk that the patient develops hyponatremia *by administering a low dose of desmopressin (i.e., less than 20 µg)*." Ferring's Presentation at Oral Argument, ECF No. 199-8 (emphasis added).

i. Preamble of Claim 1

With respect to claim 1 of the '321 Patent, the preamble announces the twin aims of the claimed invention: to (1) postpone urination in a patient; while (2) reducing the risk that the patient develops hyponatremia. See Shared Preamble ("[1] a method for inducing voiding postponement in a patient while [2] reducing the risk that the patient develops hyponatremia comprising"). The body of claim 1, which begins where the preamble ends—after the word "comprising"—reads:

> [D]elivering to the bloodstream of the patient an amount of desmopressin no more than about 2 ng/kg by intranasal, transdermal, intradermal, transmucosal, or conjunctival administration, said amount being therapeutically effective to product an antidiuretic

effect lasting for no more than between about 4 and 6 hours.

Claim 1 of the 321 Patent.

As Ferring recognizes, the reduced risk of hyponatremia risk, coupled with the invention's ability to induce an antidiuretic effect, was invoked repeatedly at patent prosecution to distinguish the prior art. See Pls.' Memo. in Supp. 198 ("The intrinsic evidence further makes clear that the preambles of claims 1 and 19 of the '321 patent—a method for inducing voiding postponement in a patient while reducing the risk that the patient develops hyponatremia comprising—are also limiting"); see also Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1370 (Fed. Cir. 2003) ("Clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation[.]"). The purpose of the Shared Preamble is to limit and more narrowly teach the "delivering to the bloodstream of the patient an amount of desmopressin no more than about 2ng/kg . . ." language from the body of claim 1.

Accordingly, the Shared Preamble is construed consistent with its plain and ordinary meaning as a statement of

purpose—dual purposes, really. It requires no further construction. See Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305-06 (Fed. Cir. 1999) (where the preamble is "intimately meshed with the ensuing language in the claim," "there is no meaningful distinction to be drawn between the claim preamble and the rest of the claim, for only together do they comprise the 'claim'").

ii. Preamble of Claim 19

The preambles of claims 1 and 19 being identical, and the claim bodies similar, claim 19's preamble serves substantially the same purpose as claim 1's. In Claim 19, however, the dual purpose of teaching a method to (1) "induc[e] voiding postponement"; while (2) "reducing the risk that the patient develops hyponatremia" is directed at particular routes of administration. The body of claim 19, which begins where the preamble ends—after the word "comprising"—reads:

> [D]elivering to the bloodstream of the patient via transdermal, intradermal, transmucosal, or conjunctival administration no more than about 1 ng/kg desmopressin to produce an antidiuretic effect for no more than about four to six hours.
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> Claim 19 of the 321 Patent.

Claim 19's preamble teaches a skilled artisan how to administer desmopressin to the blood—through different routes of

administration—to achieve the preamble's dual purpose. The preamble itself needs no further construction; its plain and ordinary meaning controls.

b. The Substantive Claims

Transmucosal

"Transmucosal," which appears in claims 2, 6, 10, and 13 of the 203 Patent, and in claims 1, 12, and 19 of the 321 Patent, is one of two claim terms for which both parties offer constructions. Serenity proposes the following construction: "delivering desmopressin by way of a mucosal tissue, such as the sublingual mucosa." Joint Disputed Claim Chart at 6. Ferring, on the other hand, proposes "absorbed across the mucosal membrane." Id. Serenity's "such as" language reflects its position that sublingual delivery of desmopressin is an example of transmucosal delivery of the drug. Ferring's construction seeks to import the additional limitation that, in order for desmopressin to be transmucosally delivered or administered, it must be *absorbed*. See Joint Disputed Claim Chart at 6.

Claim construction "begins and ends in all cases with the actual words of the claim." Becton Dickinson & Co. v. Tyco Healthcare Grp. L.P., 616 F.3d 1249, 1254 (Fed. Cir. 2010).

"Transmucosal" appears in the claims as a component of broader phrases such as "administering said composition by transmucosal . . . delivery" (claim 2 of the 203 Patent); "delivering to the bloodstream of the patient an amount of desmopressin no more than about 2 ng/kg by . . . transmucosal or conjunctival administration" (claim 1 of the 321 Patent); and "administering to a patient a pharmaceutical composition . . . by transmucosal . . . delivery" (claim 10 of the 203 Patent).

Ferring's proposal, that "transmucosal" delivery be defined to necessarily involve "transmucosal absorption" is unsupported by the language of the Common Specification, which decouples the concept of delivery of desmopressin to the mouth from absorption through the mouth. See 203 Patent at column 15 ("Pharmaceutical dosage forms of the present invention are adapted to supply the active ingredient to the oral cavity . . .*[which] may be* absorbed across the sublingual mucosa for systemic distribution" (emphasis added); see also id. at 16:24-27 ("A variety of formulations are known which are suitable for delivering other active ingredients for absorption from the oral cavity."); id. at 18:8:12-14 ("Other formulations known for delivering active ingredients for absorption from the oral

cavity are the dosage forms disclosed [ ] which comprise an orally administrable medicament").

Consistent with Serenity's proposal, "transmucosal" is referenced in the specification as a desmopressin delivery method of which sublingual is an example. For instance, the specification notes that "transmucosal include[es] buccal and sublingual (orodispersible tablets, wafers, film and effervescent formulations" (321 Patent at 23, 17); that "these amounts and ranges of desmopressin may be administered by any method known in the art, including . . . transmucosal (buccal and sublingual, e.g., orodispersible tablets, [etc]" (321 Patent at 22, 16:51-54); and that "the available evidence showed that desmopressin administered in the oral cavity (sub-lingually) was not significantly absorbed." 321 Patent p. 16, 3.

Accordingly, "transmucosal" is construed as "delivering desmopressin by way of a mucosal tissue, such as the sublingual mucosa."

transmucosal delivery/ transmucosal . . . delivery

"Transmucosal delivery," appearing in claims 2, 6, 10, and 13 of the 203 Patent, is a term Ferring proposes should be construed as "transmucosal absorption," while Serenity proposes "delivering desmopressin by way of a mucosal tissue, such as the sublingual mucosa." ECF No. 158-1 at 6.

As discussed above, repeated references by Dr. Fein to transmucosal delivery in the specification suggests he contemplated delivery as a different step in the process from absorption (see discussion immediately *supra*). Despite Ferring's contentions otherwise, "delivering" is not coextensive with "absorption." The Federal Circuit has long recognized the "common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope." See e.g., Anderson Corp. v. Fiber Composites, LLC, 474 F.3d 1361, 1369 (Fed Cir. 2007); Karlin Tech. Inc. v. Surgical Dynamics, Inc., 177 F.3d 968, 971-72 (Fed. Cir. 1999). Accordingly, because "delivery" of desmopressin need not involve actual absorption, Serenity's construction is adopted.

"Transmucosal delivery"/ "transmucosal . . . delivery" is construed as "delivering desmopressin by way of a mucosal tissue, such as the sublingual mucosa."

"delivering to the bloodstream . . . by [via] transmucosal . . . administration"

This claim term, appearing in claims 1 and 19 of the 321 Patent, uses the noun form of "administer," which, like "delivery," is not used interchangeably with "absorb" or "absorption" in the 321 Patent's specification. See Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed Cir. 2005) (claim language "must be read in view of the specification, of which they are a part."). Serenity proposes the construction "administering desmopressin by way of a mucosal tissue, such as the sublingual mucosa," while Ferring again proposes "transmucosal absorption." Joint Claim Chart at 6.

With respect to the second portion of the claim term, "by transmucosal . . . administration," there is no indication in the specification or elsewhere that Dr. Fein meant for "transmucosal . . . administration" to be limited definitionally to "transmucosal absorption." See discussion immediately *supra;*

see also Vitrionics Corp., 90 F.3d at 1582 (citing Markman, 52 F.3d at 979).

Ferring's position, that by referencing transmucosal administration Dr. Fein's invention encompasses *only* transmucosal absorption of desmopressin, is unavailing. Where a claim term is unambiguous, "we do not read limitations from the specification into the claims; we do not redefine words." Thorner v. Sony Comput. Entm't Am. LLC, 669 F.3d 1362, 1366-67 (Fed. Cir. 2012); see also Kara Tech. Inc. v. Stamps.com, Inc., 582 F.3d 1341, 1348 (Fed. Cir. 2009) ("The patentee is entitled to the full scope of his claims and we will not . . . import a limitation from the specification into the claims.").

There is no suggestion by Dr. Fein in his 321 Patent that "delivering [desmopressin] to the bloodstream" by definition encompasses absorption. To support its position that it does, Ferring cites, among other things, a portion of the 321 Patent's specification that reads, "according to a first aspect of the invention, there is provided a pharmaceutical dosage form of desmopressin adapted for sublingual absorption." 321 Patent at Column 3. But the specification also contemplates, among other things, delivery of desmopressin rectally by enema.

Neither Dr. Fein's reference to sublingual absorption nor his exhaustive listing of administration methods—such as conjunctival and rectal—serve to limit claims 1 and 19. Id. at 16:56-57. Instead, reference in these claims to delivery of desmopressin to the bloodstream "[via] transmucosal . . . administration" is an example of, rather than a limitation on, the potential sites of absorption.

"Delivering to the bloodstream . . . by [via] transmucosal . . . administration," is construed as "administering desmopressin by way of a mucosal tissue, such as the sublingual mucosa."

"transmucosal administration"/ administering . . . by transmucosal administration"

This disputed term, which appears in claim 12 of the 321 Patent, is construed as "administering desmopressin by way of a mucosal tissue, such as the sublingual mucosa." See U.S. Surgical Corp. v. Ethicon, Inc. 103 F.3d 1554, 1567-68 (Fed. Cir. 1997 (Claim construction "is not an obligatory exercise in redundancy"—courts need not "repeat or restate every claim term.")

"a dose of desmopressin sufficient to achieve a maximum desmopressin plasma/ serum concentration no greater than 10 pg/ml"

This claim term, appearing in claim 1 of the 203 Patent, is the source of intense dispute. Serenity contends that the phrase—directed at the concentration of desmopressin in a patient's blood/ plasma—has a "well-understood meaning to persons of ordinary skill in the art" and therefore requires no construction. Ferring, on the other hand, urges the Court to read into the claim a dose range from the 203 Patent's specification: "in the range of .5 ng to no greater than 20 mcg." Joint Disputed Claim Chart at 7.

"Courts do not rewrite claims." Process Control Corp v. HydReclaim Corp., 190 F.3d 1350, 1357 (Fed. Cir. 1999) ("instead we give effect to the terms chosen by the patentee."). Nor do courts "state the endpoints of [a] claimed range with greater precision than the claim language warrants." Phillips, 505 F.3d at 1377.

Our construction begins, as it must, with the language of the claim. See Vitronics, 90 F.3d at 1582 ("[W]e look to the

words of the claims themselves . . . to define the scope of the patented invention."). Neither claim 1 of the 203 Patent, nor the other asserted claims, reference a numerical dose or dose range of desmopressin. See Claim 1 of the 203 Patent ("comprising a dose of desmopressin sufficient to achieve a maximum desmopressin plasma/ serum concentration no greater than 10 pg/ml and maintaining the concentration within the range of about .5 pg/ml and 10 pg/ml for about four to six hours"). Instead, claim 1 is directed to a dose "sufficient to achieve" a maximum blood/ plasma concentration of the drug.

And while Dr. Fein listed several potential doses in the 203 Patent's specification, he did not expressly or impliedly define the maximum blood/ plasma concentration in dose terms, as required to import a limitation from the specification into the claims. See Vitronics Corp., 90 F.3d at 1582 ("[The] specification acts as a dictionary when it expressly defines terms used in the claims or defines terms by implication."); see also Hill-Rom Services, Inc. v. Stryker Corp., 755 F.3d 1367, 1372-73 (Fed. Cir. 2014) (when "nothing in the specification or prosecution history makes clear that the invention is limited to a [particular] use . . . we do not import limitations from the specification into the claims."); id. at 1373 (while "there are

no magic words" sufficient to "deviate from the plain and ordinary meaning of a claim term to one of skill in the art, the patentee must, with some language, indicate a clear intent to do so in the patent.").

Dr. Fein's references to particular dose amounts in the specification include the first sentence of the "Abstract," which begins: "The present invention is directed to a pharmaceutical composition comprising 0.5 ng to 20 µg desmopressin and a pharmaceutically acceptable carrier." 203 Patent Abstract. In the very next sentence, however, Dr. Fein writes:

> The present invention is *also* directed to a pharmaceutical composition . . . effective to establish a steady plasma/ serum desmopressin concentration in the range of from about 0.1 picograms desmopressin per mL plasma/ serum to about 10.0 pg/mL."
>
> 203 Patent Abstract (emphasis added).

Then, in the "Summary of the Invention" portion of the specification, Dr. Fein lays out several possible aspects, or embodiments, of the invention. He writes that "in one aspect, the present invention is directed to a pharmaceutical composition comprising 0.5 ng to 20 µg desmopressin and a pharmaceutically acceptable carrier."

Id. at column 2:26-30. Next, Dr. Fein recites a second embodiment directed at blood/ plasma concentrations of desmopressin: "in *another aspect*, the present invention is directed to a pharmaceutically acceptable carrier, wherein the pharmaceutical composition is effective to establish a steady [plasma] desmopressin concentration in the range of from about 0.1 picograms[to] about 10.00 picograms." Id. at column 2:30-37 (emphasis added). And a third: "in *another aspect*, the present invention is directed to an article of manufacture comprising packaging material and a pharmaceutical composition contained within the packing material[.]" Id. at column 2:38-42 (emphasis added).

Elsewhere in the 203 Patent, Dr. Fein expresses as part of his invention percentages of current recommended doses of desmopressin and resulting blood concentrations:

> "the present inventor has found that doses and plasma/ plasma/serum concentrations of desmopressin which are from 5 to 40% of the current recommended doses and resulting plasma/ plasma/serum levels are therapeutically effective, and in some cases safer . . . .
>
> 203 Patent at column 3.

According to Counterclaimants, the "5 to 40% of the current recommended doses" embodiment corresponds to a capacious dose range: anywhere from about 10 µg to 200 µg. Memo in Supp. at n. 5. But just as Dr. Fein's narrower embodiments do not limit his invention, nor does this one expand it. Rather, his invention is limited by the expressed maximum *blood concentration*, or Cmax, of desmopressin. See Notice of Allowance at 8, ECF 191-32 ("[T]he claims are distinguished over the art, as the art did not recognize achieving a Cmax of 10 pg/ml or less"); See also Phillips, 415 F.3d at 1323 ("[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.") (citing Nazomi Communications, Inc. v. ARM Holdings, PLC, 403 F.3d 1364, 1369 (Fed Cir. 2005)); see also Superguide Corp. v. DirecTV Enterprises, Inc., 358 F.3d 870, 875 (Fed. Cir. 2004) ("[A] particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.")

Where Dr. Fein does reference numerical doses of desmopressin in the specification, the doses vary widely. For example, in the "Detailed Description of the Invention" section, Dr. Fein writes:

> The daily dosage of desmopressin . . . will generally be from 0.5 or 1 µg to 1 mg per dosage form. In one preferred dosage range the dosage will typically range from 2 µg to 800 µg per dosage form and preferably from 10 µg to 600 µg. Comparatively lower doses . . .are also specifically contemplated, for example from 0.5 ng to 20
>
> Column 4:1-8.

Much of the teachings in the 203 Patent's specification, however, are directed at concentrations of desmopressin in the bloodstream. For example:

> In accordance with the present invention, plasma/serum desmopressin concentrations following administration of the pharmaceutical composition of the invention preferably range from 0.1 pg/mL to about 10.0 pg/mL, and more preferable from about 0.5 pg/mL to about 5.0 pg/mL.
>
> Column 16:46-50;
>
> [P]harmaceutical compositions that contain desmopressin in an amount that provide the above plasma/ plasma/ serum desmopressin levels may be prepared by the above methods and using the above carriers.
>
> Column 16:59-64;
>
> "[D]esmopressin can produce this essential antidiuretic effect at much lower doses and lower blood concentrations than previously thought. Therefore, lower doses and concentrations of desmopressin may be used for treating patients with all of the above conditions.
>
> Column 27.

Dr. Fein also makes efforts in the specification to explain that his invention is broad and varied. Just before reciting his claims Dr. Fein writes that the 203 Patent "is intended to embrace all such changes, modifications, and variations that fall within the spirit and broad scope of the appended claims." Column 28.

The 203 Patent does not define a particular dose range—neither expressly nor by implication—corresponding to the claimed blood/plasma range of desmopressin from claim 1. See Vitronics, 90 F.3d at 1582 ("[The] specification acts as a dictionary when it expressly defines terms used in the claims or defines terms by implication"). And "although the specification often describes very specific embodiments of the invention," the Federal Circuit has "repeatedly warned against confining the claims to those embodiments." See Phillips v. AWH Corp., 415 F.3d 1303, 1323 (Fed. Cir. 2005) (collecting cases); see also Markman v. Westview Instruments, Inc. 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996) ("The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of the claims.").

Instead, throughout the specification Dr. Fein references blood plasma/serum levels of desmopressin and newly-discovered therapeutic uses for the same. See e.g., 203 Patent at column 16:46-50 ("In accordance with the present invention, plasma/serum desmopressin concentrations following administration . . . preferably range from 0.1 pg/mL to about 10.0 pg/mL[.]"); id. at column 27 ("[D]esmopressin can produce this essential antidiuretic effect at . . . lower blood concentrations than previously thought.").

So too in claim 1 itself, which instructs a person of ordinary skill in the art to "administer[] to a patient in need thereof a pharmaceutical composition comprising a dose of desmopressin sufficient to achieve a maximum desmopressin plasma/serum concentration . . . ." 203 Patent, claim 1. There is no mention of dose or dose range. According to the Patent Examiner's Notice of Allowance, no such numerical dose range is required. See 203 Patent Notice of Allowance, ECF No. 191.32 ("[I]t would not pose an undue burden to determine what [dose] would be necessary to achieve the requisite desmopressin [concentration] as in the claims, particularly since the

examples show a linear correlation between dose and cmax.").

The patent prosecution history does not suggest Dr. Fein intended a dose limitation where one does not exist in the claim. While it is true Dr. Fein originally filed patent applications for the 203 and 321 Patents that included numerical dose ranges of desmopressin, he expressly amended those claims to remove dose-specific language. ECF No. 201-19-20. In addition, Dr. Fein amended his original claim 19 of the 203 Patent to remove the word "low" from the phrase "low dose." See Memo in Reply at 8-9. The act of broadening his claims during patent prosecution suggests an intent to claim more, not less than was originally contemplated.

Also at patent prosecution, Dr. Fein responded to an office action and characterized his claims as requiring "that a desmopressin concentration with the recited range *must be established in serum/ plasma* . . . or must be maintained for the time recited" Memo in Reply at 5. The Patent Examiner's Notice of Allowance distinguished the 203 Patent from the prior art on the basis of its recited blood/ plasma concentration (expressed

as Cmax) of desmopressin. See ECF 191-32 ("[T]he claims are distinguished over the art, as the art did not recognize achieving a Cmax of 10 pg/ml or less").

The linear relationship between dosage of desmopressin and blood/ plasma concentration of the drug—based on various routes of administration and associated bioavailabilities—allows a person of ordinary skill in the art to practice Dr. Fein's low dose discovery. See Notice of Allowance, ECF No. 191.32 ("[I]t would not pose an undue burden to determine what [dose] would be necessary to achieve the requisite desmopressin [concentration] as in the claims, particularly since the examples show a linear correlation between dose and cmax.").

Accordingly, "a dose of desmopressin sufficient to achieve a maximum desmopressin plasma/ serum concentration no greater than 10 pg/ml" has a well-understood meaning to a person of ordinary skill in the art. It requires no construction.

"desmopressin . . . in an amount . . . sufficient to establish a maximum serum/ plasma desmopressin concentration no greater than 10 pg/ml"

This claim language, appearing in claim 10 of the 203 Patent, is part of a method of treatment claim directed at a durational blood concentration of desmopressin to achieve an antidiuretic effect. The claim language is nearly identical to that of claim 1 of the 203.

The parties' positions are the same with respect to the remaining claims that recite blood/ plasma concentrations of desmopressin as they were immediately *supra*—Ferring seeks a dose limitation and Serenity proposes the claims as written have a plain and ordinary meaning. This phrase, "desmopressin . . . in an amount . . . sufficient to establish a maximum serum/ plasma desmopressin concentration no greater than 10 pg/ml," like the above-construed "a dose of desmopressin sufficient to achieve a maximum desmopressin plasma/ serum concentration no greater than 10 pg/ml" from claim 1 of the 203 Patent, has a well-understood meaning to a person of ordinary skill in the art. For the same reasons discussed above, the term requires no further construction.

"desmopressin pharmaceutical composition . . . in an amount . . . sufficient to establish a serum/ plasma concentration no greater than about 5 pg/ml"

This claim language, appearing in dependent claim 12 of the 203 Patent, is directed to a plasma concentration "no greater than about 5pg/ml." For the reasons discussed above (see discussion *supra* at 28-37), the claim term has a meaning understood to a person of ordinary skill in the art and requires no further construction.

"desmopressin . . . in an amount . . . sufficient to establish a maximum serum/ plasma desmopressin concentration greater than 0.1 pg/ml and less than 10 pg/ml"

This claim language, appearing in claim 13 of the 203 Patent, is part of a method of treatment claim directed at transmucosal or intradermal delivery of desmopressin to achieve a particular blood/ plasma concentration of the drug for a particular period.

The claim term in dispute is "desmopressin . . . in an amount . . . sufficient to establish a maximum serum/ plasma

desmopressin concentration greater than 0.1 pg/ml and less than 10 pg/ml."

For the reasons discussed above (see discussion *supra* at 28-37) this claim term—directed at a plasma/ concentration "no greater than about 10 pg/ml"—has a meaning understood to a person of ordinary skill in the art. It requires no further construction.

"delivering to the bloodstream of the patient an amount of desmopressin no more than about 2 ng/kg . . . said amount being therapeutically effective to produce an antidiuretic effect"

This claim language, appearing in claim 1 of the 321 Patent, is part of a method of treatment claim directed at an amount of desmopressin in the patient's bloodstream—"no more than about 2 ng/kg"—to produce an antidiuretic effect for a period of approximately four to six hours. 321 Patent at column 28.

Ferring proposes that this claim term be construed as "a dose of desmopressin in the range of 0.5 ng to no greater than 20 mcg." Joint Disputed Claim Chart at 10. Serenity, on the

other hand, proposes that the numerical desmopressin concentration—"no more than about 2 ng/kg"—be construed to include a standard human body weight estimate of 70 kg. Id.

The disputed claim term is similar in kind to the 203 Patent terms resolved above. With respect to Ferring's proposed dose limitation, the issue here is the same: whether the claim as written, when viewed in light of the Common Specification and the prosecution history, includes a dose limitation. The Court concludes that it does not.

First, there is no dose limitation in claim 1 of the 321 Patent and the Court finds no express intent in the Common Specification to redefine its scope to include one. Vitrionics, 90 F.3d at 1582 ("[W]e look to the words of the claims themselves . . . to define the scope of the patented invention."); Liebel-Flarsheim Co. v. Medrad Inc., 358 F.3d 898, 906 (Fed. Cir. 2004) ("Redefinition, or lexicography, requires that the patentee must 'clearly express an intent' to redefine the term.").

Ferring contends that the Common Specification "provides that the maximum effective dose range to provide [the

claimed] plasma/serum desmopressin concentration . . . is 0.5 ng to 20 µg." Memo in Opp. at 17. As discussed above, Dr. Fein included in the Common Specification desmopressin dosage examples that were both lower and higher than Ferring's suggested dose limit. See discussion *supra* note 2. There is no reason here, as there was no reason there, to read into the claim an unexpressed dose limitation. Dr. Fein recited the metes and bounds of his invention in terms of blood/plasma concentration, not dose. See Stanacard, LLC v. Rebtel Networks, AB, 680 F.Supp.2d 483, 487 (S.D.N.Y. 2010) ("The language of a patent claim circumscribes the metes and bounds of the patent owner's property right by defining the bounds of the claim scope.").

Ferring cites an earlier patent application where Dr. Fein included, but later removed, a dose range of desmopressin of 0.5 ng to 20 µg. Memo in Opp. at 18. Ferring contends that "at no point during the prosecution history of the patents in suit did Dr. Fein explicitly seek to claim a dose of desmopressin higher than 20 µg." Memo. in Opp. at 18. Just as he removed earlier references to dose amounts from the 203 Patent's original application, Dr. Fein did the same here. The claims were changed to method claims and their dose ranges removed. See

Reply Memo. at 8-9. The act of broadening claims at patent prosecution through amendment suggests an intent to claim more, not less, than was originally contemplated.

With respect to Serenity's proposal, that claim 1 be read to include the "standard human body weight of 70 kg," such clarifying language is appropriate. A standard human body weight, according to Serenity, assists in calculating individual desmopressin dosage to achieve a blood concentration "no more than about 2 ng/kg." See memo. in supp. at 16. Ferring does not specifically object to the inclusion of a standard human body weight. Supplied with a standard human body weight, persons of ordinary skill can readily administer desmopressin through the method Dr. Fein discovered. Serenity's proposal finds support in both the Common Specification (see 203 Patent at column 20 (referencing "the standard 70 kg weight estimate upon which the doses and blood levels of desmopressin in this study are based")), and in the medical literature cited (see e.g., ECF 170-11 ("When considering 'normal' measurements, an average 70 kg individual who sleeps 8 hours a night is the basis for these values"; ECF 170-12 (substantially same)).

For the reasons set forth, Serenity's proposed construction is adopted. The claim term "about 2 ng/kg" is construed as "about 2ng/kg based on the standard 70 kg human body weight estimate." The rest of the claim term has a well-understood meaning to persons of ordinary skill in the art and requires no further construction.

"delivering to the bloodstream of the patient an amount of desmopressin no more than about 1 ng/kg"

This claim term, appearing in claim 2 of the 321 Patent, is construed consistent with claim 1 of the 321 Patent (see discussion immediately *supra*). Serenity's proposed construction is adopted. The claim term "about 1 ng/kg" is construed as "about 1 ng/kg based on the standard 70 kg human body weight estimate." The rest of the claim term has a well-understood meaning to persons of ordinary skill in the art and requires no further construction.

"an amount of desmopressin sufficient to produce in the patient a urine osmolality ranging above about 300 mOsm/kg"

This claim term, appearing in claim 8 of the 321 Patent, has a well-understood meaning to persons of ordinary skill in the art and, for the same reasons discussed above, requires no further construction. See discussion *supra* at 39-43.

"delivering to the bloodstream of the patient . . . no more than about 1 ng/kg desmopressin to produce an antidiuretic effect"

This claim term, appearing in claim 19 of the 321 Patent, is construed consistent with claim 1 of the 321 Patent (see id.): "about 1 ng/kg" is construed as "about 1 ng/kg based on the standard 70 kg human body weight estimate."

"about 2 ng/kg desmopressin"

This claim term, appearing in Claims 1 and 17 of the 321 Patent, is construed consistent with the identical claim term discussed above: "about 2 ng/kg" is construed as "about 2 ng/kg based on the standard 70 kg human body weight estimate." See discussion *supra* at 40-43.

"about 1 ng/kg desmopressin"

This claim term, appearing in claims 2 and 19 of the 321 Patent, is construed consistent with the identical claim term discussed above: "about 1 ng/kg" is construed as "about 1 ng/kg based on the standard 70 kg human body weight estimate." See discussion *supra* at 45.

VI. Conclusion

The Shared Preamble and the Asserted Claims of the 203 and 321 Patents are construed consistent with this Opinion.

It is so ordered.

New York, NY
January 22, 2019

ROBERT W. SWEET
U.S.D.J.